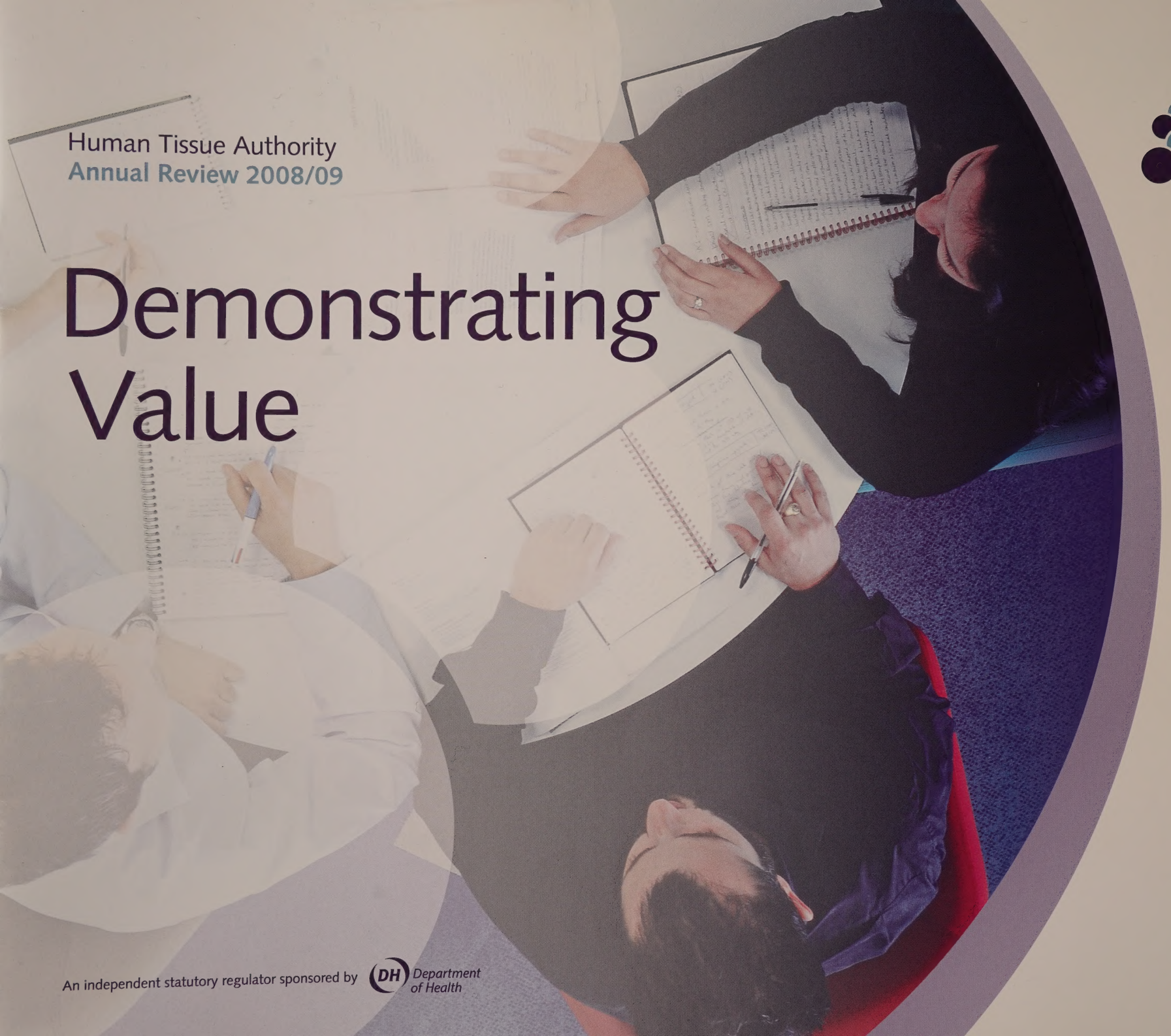
Human Tissue Authority
Annual Review 2008/09

Demonstrating Value



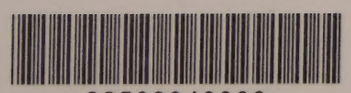
HTA
Human Tissue Authority

An independent statutory regulator sponsored by DH Department of Health

The Human Tissue Authority (HTA) is an independent regulator. We are responsible for licensing organisations that store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We are also responsible for approving organ and bone marrow donations from living people.

We provide advice and guidance about two laws: the Human Tissue Act and the European Union Tissue and Cells Directives. These laws ensure human tissue is used safely and ethically, with proper consent. Our aim is to set standards that are clear and reasonable, and in which both the public and professionals can have confidence.

This Annual Review covers the period 1 April 2008 to 31 March 2009. The HTA's full Annual Report and Accounts are available at: www.hta.gov.uk/publications/annualreviewsandreports.cfm



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Our **determination** to be **transparent** and **accountable** means we have continually engaged and consulted those we regulate

Chair and Chief Executive's introduction

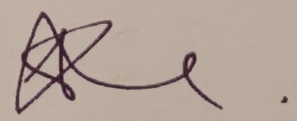
Welcome to the HTA's fourth Annual Review, which describes our achievements and activities in 2008/09. This has been a challenging year for us, particularly because of the substantial growth in our remit under the European Union Tissue and Cells Directives. Our resources have been stretched to their limits, but we have continued to streamline our systems and processes so that we can operate as efficiently, effectively and economically as possible.

In the three years since the HTA was established, we have built a firm regulatory foundation based on the principles of Better Regulation. At the end of 2008 the Better Regulation Executive assessed our compliance with these principles and the statutory code of practice for regulators. We were encouraged that the review team endorsed the way we develop and improve our advice and guidance, and engage our stakeholders to raise awareness and understanding. We were also pleased they recognised that our risk-based approach keeps the regulatory burden on establishments to a minimum. Many of the people we regulate have told us that our regulatory approach has had a positive impact on standards.

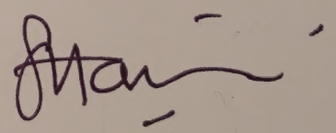
Our determination to be transparent and accountable means we have continually engaged and consulted those we regulate. We want and need to understand the challenges they face so that we can put our regulation into context. Examples of our engagement with stakeholders during 2008/09 include updating our codes of practice, introducing a new code on research, developing our new licensing methodology, improving our website and working with other organisations to streamline regulation. We hope you agree that this Annual Review captures how we continue to work together with others.

Our revised codes of practice will come into force during the coming year, and, based on feedback from the last consultation, we will be reviewing our licence fee model.

In these straitened times, our key aim will be to continue to provide a high quality service that represents value for money for both licence holders and tax payers, whilst ensuring a clear robust regulatory framework that maintains public confidence.



Adrian McNeil
Chief Executive



Shirley Harrison
Chair

The year at a glance

April – June

- The Board of Authority Members agrees our Strategic and Business Plans.
- Guide to our key messages published to help professionals explain our work to the public.
- Work begins to revise all our codes of practice and to create a new code on research.
- HTA continues to work with the European Commission to develop interpretation of aspects of the EU Tissue and Cells Directives.
- Four new Authority Members join the Board.

July – September

- Organisations collecting tissue for patient treatment (such as cord blood) are required to apply for an HTA human application licence.
- Organisational review completed to ensure that we have the right structure and staffing to meet our statutory remit; HR and IT strategies developed and agreed.
- Consultation on revised codes of practice begins and workshops held.
- Summary inspection reports published for the five licensed sectors.
- Public Authority meeting and report-back event held in London.
- Reaccreditation of 115 Independent Assessors completed.

October – December

- Consultation completed on the revised codes of practice.
- Workshops held to develop an improved way of licensing.
- New licence fee consultation begins.
- Annual conference for Independent Assessors attended by Ann Keen MP, Parliamentary Under Secretary for Health Services.
- HTA inspected by the Better Regulation Executive.
- Users of the HTA website asked for their views on how we can improve it.

January – March

- Training event for Designated Individuals (DIs) in the human application sector held in Birmingham.
- HTA contributes to the development of a 'Regulatory Route Map' for the use of stem cells in research and patient treatment.
- HTA evaluates impact of human tissue legislation and our regulation on research.
- Public Authority meeting held in Manchester.
- Consultation completed on new licence fee structure.

171 human application licences

46 procurement licence applications

Ann Smith,
Clinical Scientist and
Head of Stem Cell Laboratory,
Royal Marsden NHS Foundation Trust, Surrey

Fulfilling our role in implementing human tissue legislation

I am responsible for the laboratory elements of the haematopoietic stem cell transplant programme at the Royal Marsden NHS Foundation Trust, and I am the DI for the human application licence. We treat adults and children with several different types of cancer of the blood and bone marrow, such as leukaemia, as well as some solid tumours.

The HTA regulates all aspects of our work, including stem cell collection, processing, storage and distribution; as well as consent and governance. Part of my job is to make sure that the unit is ready for inspection, but I think of this as an ongoing process – it is important to focus on quality every day. The European legislation is very complicated in this area and the HTA tries to make sense of it and pull out the salient elements for us to implement.

Regulation has driven up standards in this area. We have always tried to achieve high standards, but having them specified and achieving them gives the team confidence. Before regulation there was disparity in the way different groups interpreted guidelines, whereas now there is much more consensus in the sector. Being licensed gives the team reassurance that we are performing well.

We were the first stem cell transplant establishment to be inspected by the HTA. Since that first inspection two years ago, the HTA has taken advice from experts in the field and their understanding has grown a great deal. We had our second inspection recently and the HTA staff were familiar with the work, making for a balanced and thorough inspection with good communication on both sides. Although inspections are always stressful, having a licence from the HTA makes it worthwhile.

Dr Ann Smith is the DI for the human application licence at the Royal Marsden NHS Foundation Trust. DIs supervise the activities that are carried out at licensed establishments. The HTA licenses 171 establishments in the human application sector.

In the last year we have fulfilled our role in implementing human tissue legislation; highlights include:

- Licensing organisations that collect tissues and cells for patient treatment (human application). 46 organisations applied for a procurement licence.
- Issuing two regulatory alerts to establishments in the human application sector. Alerts are issued to provide information on potential risks and set out actions that establishments need to take to minimise them.
- Providing evidence to the House of Lords Select Committee on the European Union's inquiry into communication on organ donation and transplantation. The European Commission adopted a proposal for an Organ Donation Directive in December 2008.
- Contributing to the Department of Health report on cord blood banking in the UK.
- Holding Tissue and Cells Working Group meetings with other regulators including the Medicines and Healthcare products Regulatory Agency.

1,058 living organ donations approved

57 bone marrow donations approved

Lisa Burnapp,
Consultant Nurse,
Living Donor Kidney Transplantation,
Guy's and St Thomas' NHS
Foundation Trust, London

Operating efficiently, effectively and economically

I head a team of nurses that coordinate the living-donor kidney programme at Guy's and St Thomas' NHS Foundation Trust. My role is to liaise with donors and recipients and carry out a primary assessment to find out if they are suitable to proceed. At the hospital we have built a reputation for dealing with more complex recipients who may otherwise be excluded from transplantation. For these patients, a planned living-donor transplant may offer them the only opportunity for a life free from dialysis.

The HTA's independent assessment process gives reassurance that we have truly upheld the best interests of the donor. Working with someone independent gives us a safeguard that we are following best practice. Without an external arbiter we would have no benchmark; the HTA gives us a national benchmark.

The information the HTA provides for the public is very important – we use the living-donor leaflet all the time and I regularly direct people to the HTA website because it is very accessible.

It has been a privilege to be a member of the HTA Transplant Working Group. Everyone in the group has a different expertise and we listen carefully to each others' views. We work through problems or address issues that may have come up and it is rewarding to affect clinical practice at a grass roots level.

The HTA wants to find out what the challenges are, and talk to us rather than dictate what happens. Initially the transplant community was very anxious about the amount of time it would take for approvals. The HTA listened to our concerns and promised to turn around decisions within five days, but in reality it is almost always much quicker.

The HTA has worked hard to minimise bureaucracy and take a pragmatic approach. The codes of practice also provide very clear guidance and help to clarify any grey areas in the legislation.

Lisa Burnapp is a Consultant Nurse for the living-donor programme at Guy's and St Thomas' NHS Foundation Trust. Keith Rigg is a Transplant Surgeon in Nottingham, President of the British Transplantation Society and an Authority Member. Lisa and Keith are members of the HTA's Transplant Working Group.

In the last year we have operated efficiently, effectively and economically; highlights include:

- Approving 1,058 reports from Independent Assessors (IAs) and 57 reports from Accredited Assessors (AAs). (IAs and AAs interview donors and recipients.)
- Holding a consultation on the HTA's new licence fees. Responses came from individuals, professional and representative bodies, and organisations holding a number of licences. As a result, the HTA reduced fees for satellites and decided not to charge for third party agreements in the human application sector during 2009/10.
- Removing the requirement for anatomy establishments to provide data that is no longer needed.
- Developing a new system to improve the way that we handle and log enquiries.

142 research licences

192 inspections

Nalin Thakker,
Professor of Molecular Pathology and Genetics and Consultant Histopathologist,
St Mary's Hospital, Manchester

Driving up standards at licensed organisations

I carry out research on diseases of the head and neck, and I am the DI for the research licence. Because of my work I fully appreciate the immense value of using human tissue in research.

HTA regulation has certainly helped drive up standards. In the past, individual laboratories here had varied practices, but now we have institution-wide policies and procedures, a clearly defined structure for accountability, and training for all staff. This is not cost-free, and you have to balance benefit against risks, but overall I feel it has been worth it. The research sector is relatively low risk, so I think it is appropriate that the HTA works in a risk-based way and has a light touch.

I also advise the National Research Ethics Service (NRES) on matters relating to the HTA; and as part of this role, I sit on a joint NRES–HTA group where we discuss issues that are of common interest and concern. I think this is extremely important in providing a consistent message and a complementary approach that facilitates research.

Researchers still have some misconceptions about the Human Tissue Act. I come across researchers who say they cannot conduct research because of the Act. They are surprised to learn that not only is this not true, but the legislation has in fact clarified issues that have previously hindered research. The Act actually facilitates research.

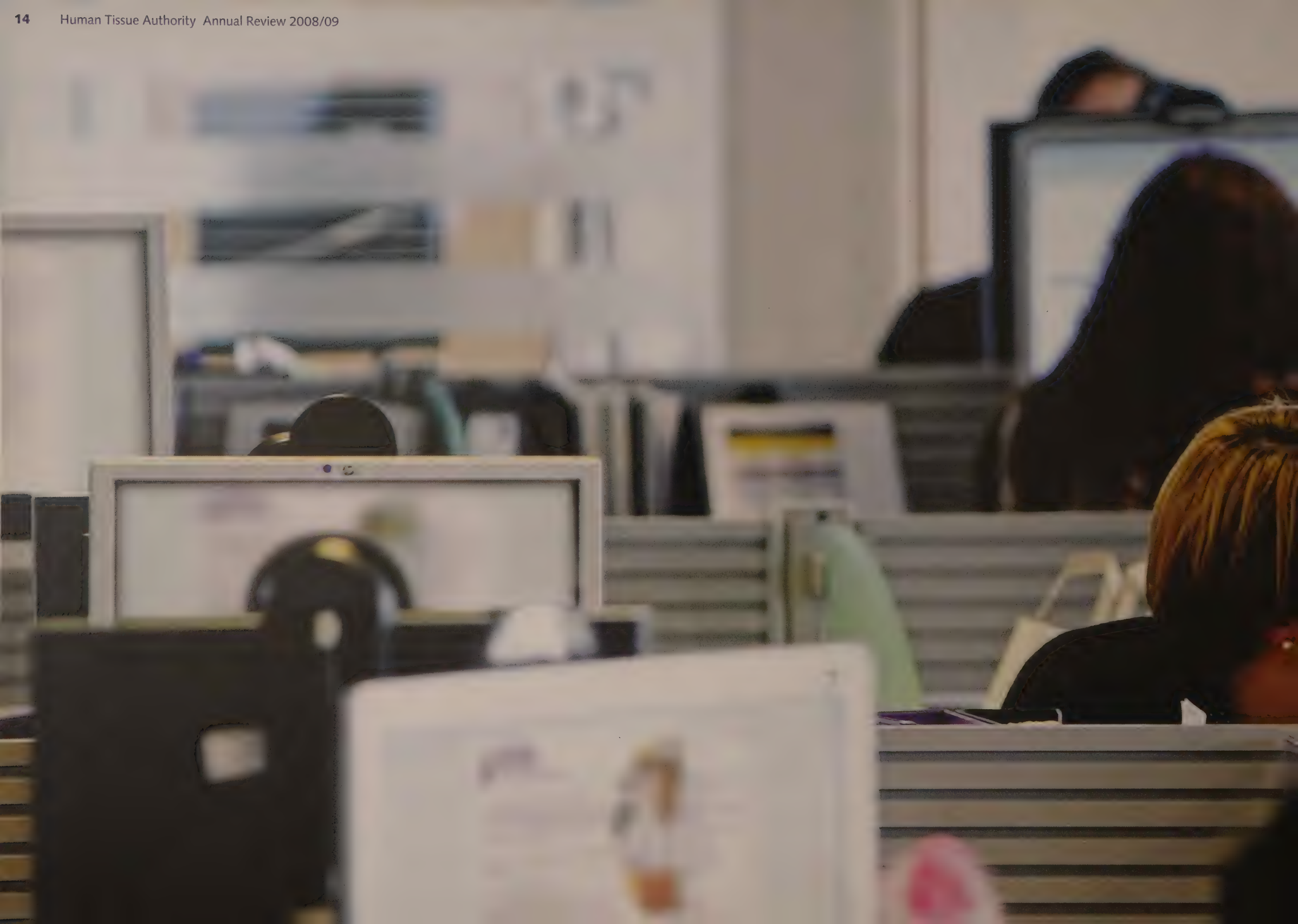
Researchers and their institutions should see themselves as partners to the HTA to help improve practice. The wide consultation exercises that the HTA has undertaken on various issues, such as the new research code of practice, are very important in developing this relationship.

It is important for the public to know that this area is regulated. Standards of ethics change with time, and what was acceptable in the past is not acceptable now.

Professor Nalin Thakker is the DI for the research licence at St Mary's Hospital in Manchester. The HTA licenses 142 establishments in the research sector.

In the last year we have helped drive up standards at licensed organisations; highlights include:

- Completing 90 phase one (desk-based) inspections and 102 phase two (site-visit) inspections across the five licensed sectors. Inspections are usually scheduled according to assessed risk; however they may also be scheduled randomly or on a reactive basis following receipt of information.
- Publishing five summary inspection reports – one for each licensed sector. The reports provide information for licensed establishments on what lessons can be learnt and how standards can be improved.
- Developing a new policy on the regulation of acellular tissues and cells for use in human application. This regulation ensures that any products can be traced to the person that they came from, and are rigorously tested before they are used to treat patients.



17 public display licences

4,800 e-newsletter subscribers

Robert Devčić, Founder and Director of GV Art, London

Providing advice and guidance to the regulated sectors

I have overall responsibility for the gallery and looking after 30 artists, and I am the DI for the public display licence. We are a commercial gallery which has used human tissue in our exhibits. We have gone to great lengths to keep the dignity of the material and have never lost sight of the fact that they are the remains of people.

When we were first considering showing an exhibition that used human tissue I was relieved to find out about the HTA, and it was only then I felt confident enough to seriously think about working with the subject. Regulation has made me feel protected and more confident; in the US it isn't clear what you can and can't do, whereas here it is very clear. When I got in touch with the HTA everyone I spoke to was very helpful. I had already read the Human Tissue Act but I found it completely overwhelming and couldn't see how it applied to my situation. The people I spoke to at the HTA put everything into perspective for me, using everyday language. Each time I had a question they have always explained how to apply the Act to that situation in practical terms.

The HTA is absolutely accessible and responsive, and sometimes gets back within hours. Language and tone is important as well, and their guidance is straightforward and written in plain English. Nevertheless, when you are not used to reading this type of guidance it helped me to get someone at the HTA to provide clarification.

The licence fee is a lot of money, but I have looked at HTA accounts and understand that it costs to keep regulating. Although the exhibition is finished, I am proud I have a licence and will keep it because it gives me the option of an exhibition in future.

Robert Devčić is the DI for the public display licence at GV Art. Caroline Browne is one of the Heads of Regulation at the HTA, and provided advice and guidance to GV Art during their licence application and inspection. The HTA licenses 17 establishments in the public display sector.

In the last year we have provided advice and guidance to the regulated sectors; highlights include

- Holding a training event for DIs in the human application sector. 80 DIs attended.
- Working with the Department of Health and other regulators to develop the first version of a Regulatory Route Map for stem cell research. The route map has been produced as a reference tool for those who wish to develop a programme of stem cell research and manufacture, ultimately leading to clinical application.
- Publishing revised guidance on the definition of relevant material under the Human Tissue Act.
- Producing six issues of our e-newsletter. The e-newsletter is the main route for communicating changes to our regulatory policy and is sent to more than 4,800 subscribers.

33 anatomy licences

2 public Authority meetings

David Hinchliffe,
Manager and Prosector
for Medical Teaching Unit,
University of Sheffield

Supporting public confidence

I am the DI for the anatomy licence at the University of Sheffield. My role is really varied, and includes everything from taking the calls from the public, to dealing with the legal profession and GPs, and carrying out dissection.

One of the main attractions for medical students studying here is the opportunity to dissect human bodies. Not all medical schools do this now, but we believe it is important that students understand the anatomy of a real body. We explain to them that the dignity of the deceased must never be compromised and it is my role as DI to make sure this is the case.

Above all they are taught to show respect. The students know they are in an extremely privileged position to be learning anatomy from a real human body. Knowing that this area is regulated is important for public confidence.

We get a lot of calls from members of the public who want to donate their body to medical science, and some of these are passed on to us by the HTA.

The anatomy code of practice is useful – it tells us what the HTA want, how to do it and we can refer back to it if we are not sure. The anatomy summary inspection report has also given us insight into what standards are expected and where there are shortfalls.

We always worked to high standards, but the HTA has given us a framework to operate under. I valued becoming a DI because it gave me more authority to say how things should be done.

The HTA has made me aware of the need for more regular auditing and checking, and, although we have never had a problem, the framework that we now work to means the likelihood of problems occurring is even more remote.

David Hinchliffe (right) is the DI for the anatomy licence at the University of Sheffield. Stephen Cobb (left) works at the HTA and regularly speaks to members of the public who wish to donate their body to medical science. The HTA licenses 33 establishments in the anatomy sector.

In the last year we have supported public confidence; highlights include:

- Holding two Authority meetings in public – in London and Manchester – and making all Authority papers available on our website.
- Asking users their views on the HTA website, in order to improve the clarity of the information and make it easier for them to find what they are looking for.
- Being inspected by the Better Regulation Executive (BRE) to assess how well we are following the principles of Better Regulation. BRE endorsed the HTA's regulatory approach.
- Developing a guide to our key messages to help professionals to explain the HTA's role to the public in clear and accessible language.
- Working with the Department of Health, NHS Blood and Transplant and other key stakeholders to develop a new policy framework on directed donation of organs after death.

228 post mortem licences

179 responses to codes of practice consultation

Terry Johnson,
Mortuary Manager,
Hull Royal Infirmary

Working with stakeholders to improve regulation

I manage the mortuary service for two local authorities and two major hospitals; and my job includes dealing with financial planning, legislation and health and safety issues.

When I first read the Human Tissue Act I felt very apprehensive. My profession wondered what the HTA would be like and eagerly awaited their first guidance document. When I read the post mortem code of practice the tone was really reassuring, it was nothing to be frightened of; it was just what we were already doing.

I helped the HTA when it first started inspecting by acting as a Specialist Advisor. I found it absolutely fascinating as I got to see what others in the sector were doing, and gained insight into the way HTA Regulation Managers work and apply standards. It has made me look forward to being inspected because I know that Regulation Managers aren't looking to trip you up; instead they look at what we do with a fresh pair of eyes. Inspection results should be welcomed by everyone because although you might be doing OK, you can always improve.

I took part in discussions about the licensing of emergency mortuaries and I was impressed at the HTA's flexible approach. All the major stakeholders were involved and they had ideas about how we could get licensed quickly. But we had to see how it worked in practice – I was involved in testing the process and recommending changes.

The HTA listens to what my profession says, and even if they don't always agree with you, they welcome different points of view. The consultations that the HTA has run are important and have been very good. I have taken part in the codes of practice consultation, and in the post mortem working group. The HTA does its bit in putting these consultations out, so it is important for people to respond.

Terry Johnson is the Mortuary Manager at Hull Royal Infirmary, which is licensed by the HTA to carry out post mortems. Dr Sandy Mather is Director of Regulation at the HTA; the regulation directorate leads the HTA's licensing and inspection programme. The HTA licenses 228 establishments in the post mortem sector.

In the last year we have worked with stakeholders to improve regulation; highlights include:

- Completing a consultation on the revised versions of our codes of practice. We received 179 consultation responses and 100 people attended the consultation workshops.
- Undertaking a project to evaluate the impact of human tissue legislation and HTA regulation on research. 295 people took part via telephone and online surveys.
- Holding workshops with the licensed sectors to discuss the HTA's licensing methodology. Based on the feedback we received we decided to change from a fixed-term system of licensing to a continuous one.
- Holding our second annual Independent Assessor conference. Ann Keen MP, Parliamentary Under Secretary for Health Services, spoke at the event.
- Setting up a post mortem working group, including representatives from relevant professions, to work together on key issues for the sector.

The year in numbers

Financial summary of the HTA's operations in 2008/09

Income	£k
Licence fee income	3,719
Government grant-in-aid	918
Other income	71
Total income	**4,708**
Expenditure	
Staff costs	2,734
Operational and administrative costs	1,790
Total expenditure	**4,524**
Operational surplus	**184**

This is a summary only. The HTA's full Annual Report and Accounts are available at: **www.hta.gov.uk/publications/annualreviewsandreports.cfm**

Licensing and inspections

Number of licensed organisations by sector in 2008/09 and 2007/08

Sector	**2008/09**	**2007/08**
Anatomy	33	31
Human application	171	119
Post mortem	228	220
Public display	17	9
Research	142	129
Total	**591**	**508**

Number of licensed organisations (excluding satellite sites):	591
Number of members of the HTA regulation directorate:	23
Ratio of licensed organisations to regulation staff:	26:1
Number of phase 1 (desk-based) inspections:	90
Number of phase 2 (site-visit) inspections:	102
Total number of inspections undertaken by the HTA:	192

Engaging stakeholders

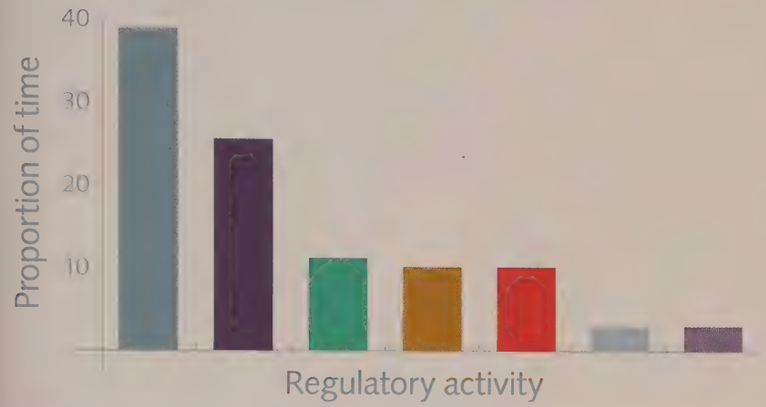
4 million hits on HTA website

4,800 e-newsletter subscrib

158,000 unique visitors to HTA website

1,300

What proportion of staff time was spent on different types of regulatory activity?



Licensing advice and guidance:	38%
Phase 2 (site-visit) inspections:	25%
Licensing enforcement:	11%
Advice and guidance in response to enquiries:	10%
Internal activities:	10%
Phase 1 (desk-based) inspections:	3%
Licence variations:	3%

120 media enquiries received

enquiries to HTA enquiries mailbox

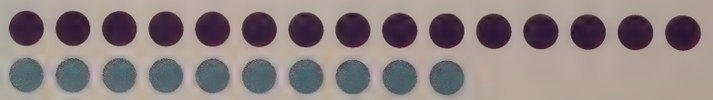
Transplants

Ratio of IAs : AAs : Members of HTA Transplants Approvals Team (38:14:1)

Number of Independent Assessors (IAs):	115
Number of Accredited Assessors (AAs):	42
Number of members of HTA Transplants Approvals Team:	3

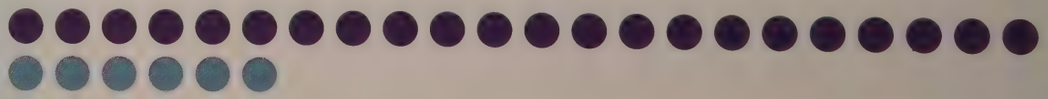
The Tranplants Approvals Team deals with annual accreditation, enquiries, requests for information, and approvals, including complex cases.

Number of IA reports approved by HTA:	1,058
Number of AA reports approved by HTA:	57
Ratio of IA and AA reports approved to HTA transplant staff:	372:1



Number of altruistic donations approved by the HTA in 2008/09: 15

Number of altruistic donations approved by the HTA in 2007/08: 10



Number of paired / pooled donations approved by the HTA in 2008/09: 22

Number of paired / pooled donations approved by the HTA in 2007/08: 6

The year ahead

2009/10 will be another demanding and challenging year. During the year we plan to:

Implement legislation

- Evaluate all new licence applications within three months.
- Contribute to the development of the EU Organ Donation Directive.

Raise standards

- Publish summary inspection reports to share learning.
- Complete a risk-based schedule of inspections.

Operate efficiently, effectively and economically

- Complete a review of our licence fee model by engaging our stakeholders in workshops and consultations.
- Launch a new system to streamline and improve our internal processes and the information we collect about stakeholders.
- Make further improvements to the approvals system for transplants.

Provide advice and guidance

- Launch the revised versions of our codes of practice and a new code on research.
- Hold a conference for the post mortem sector.
- Update our Guidance for transplant teams and Independent Assessors.

Support public confidence

- Launch our updated website and review the content of the whole site.
- Evaluate public and professional opinions about our regulation.
- Review and improve our procedures for handling complaints.

Work with stakeholders

- Contribute to the Organ Donation Taskforce Programme Delivery Board.
- Hold a workshop with organisations from the private sector, to develop a better understanding of the issues they face.

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